PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

14/(3) Declaration
Jd
1-20-95

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| In re Application of: J. M. Steinke, A.P. Shepherd | § | Examiner: K. Hantis |
| Serial No.: 07/953,680 | § | Group Art Unit: 2505 |
| Filed: September 29, 1992 | § | |
| For: METHOD AND APPARATUS FOR DIRECT SPECTROPHOTOMETRIC MEASUREMENTS IN UNALTERED WHOLE BLOOD | § | Atty. Dkt.: UTSK:142/BAH |

**CERTIFICATE OF MAILING**
**37 C.F.R. § 1.8**

**I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: The Commissioner of Patents and Trademarks, Washington, D.C. 20231, on the date below:**

**December 15, 1994** — **David D. Bahler**
**Date**

## DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Sir:

I, A. P. SHEPHERD, do hereby declare and state:

1. I am a co-inventor of the above-identified patent application, and am the President and Chief Executive Officer of A-VOX Systems, Inc., a business that has continuously manufactured biomedical instrumentation since 1977.

2. A-VOX Systems, Inc. is the exclusive, world-wide licensee for the invention disclosed and claimed in the above-identified

patent application, and has successfully developed the first of a series of products based on this invention.

3. In particular, A-VOX Systems, Inc. has developed the AVOXimeter 1000, a compact oximeter designed for the cardiac catheterization laboratory, and placed the product on the market in January of 1993. Exhibit A attached hereto is a brochure for the AVOXimeter 1000. The AVOXimeter 1000 was demonstrated to Examiners Hantis and McGraw during the Examiner interview of January 19, 1994.

4. The AVOXimeter 1000 is an oximeter that generates a plurality of monochromatic light wavelengths including an absorbance subset of wavelengths that have been selected by their ability to distinguish constituent components within blood being tested, and by their ability to minimize the effects of radiation scattering and to maximize radiation absorbance by components of blood being tested. It also operates to generate a scattering subset of wavelengths that have been selected to maximize the effects of radiation scattering by unaltered whole blood being tested relative to the effects of radiation absorbance by unaltered whole blood. The oximeter operates to irradiate a sample of unaltered whole blood of unknown composition with the absorbance and scattering subsets of wavelengths, and operates to detect the intensities of the light wavelengths after the light has passed through a depth of the sample, at a distance from the

sample, and over a detecting area, all chosen to minimize the effects of radiation scattering by unaltered whole blood. Finally, the oximeter calculates concentrations of the constituent components of a sample of unaltered whole blood corrected for the effects of radiation scattering, based upon detected intensities of each of the plurality of light wavelengths (including both the absorbance subset and scattering subset), and based upon predetermined molar extinction coefficients for each of the constituent components at each of the plurality of radiation wavelengths. On information and belief, the AVOXimeter 1000 embodies the elements of at least claim 1 presently pending in the above-identified patent application.

5. Without the aid of distributors, and using only direct-mail advertising, A-VOX Systems, Inc. sold approximately 34 AVOXimeter 1000's to hospitals in the United States in 1993. This resulted in cash receivables totalling $261,513 for the oximeter and disposable optical cuvettes used with the oximeter.

6. In the first nine months of 1994, A-VOX Systems, Inc. has sold approximately 67 AVOXimeter 1000's, resulting in accounts receivable of $537,680, for the oximeter and disposable cuvettes. This represents a 100% increase over the cash receivables for the entirety of 1993.

7. In addition, A-VOX Systems, Inc. has received an offer from Instrumentation Laboratory Company to licensee the technology disclosed and claimed in the above-identified patent application. Instrumentation Laboratory Company is a major manufacturer and marketer of blood gas analyzers throughout the world, and is the assignee of Brown *et al.*, U.S. Patent No. 4,134,678, of record in the above patent application. While no formal license agreement has been reached to date, royalty rates on the order of 5% to 6% of the incremental value added by the licensed technology are presently contemplated by both parties. At present, this converts to a payment of between $250 and $300 per unit sold by Instrumentation Laboratory Company. Letters dated July 18, 1994 and August 24, 1994 from Mr. Charles F. Mountain, the Director of Business Development, Critical Care Business Unit of Instrumentation Laboratory Company, memorializing the agreement between A-VOX Systems, Inc. and Instrumentation Laboratory Company, are collected in Exhibit B attached hereto.

8. In addition, the invention disclosed and claimed in the above-identified patent application is currently being evaluated for possible licensing by Ciba Corning and Abbott laboratories.

9. I hereby declare that all of the statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like are punishable by fine and/or imprisonment under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-identified application, or any patent issuing therefrom.

12 Dec 1994
Date

A. P. Shepherd

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